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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,628	MOSS ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1, claim(s) 1-13, drawn to a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41, classified in class 424, subclass 199.1.

Group 2, claim(s) 1 and 14, drawn to pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *vif*, classified in class 424, subclass 199.1.

Group 3, claim(s) 1 and 14, drawn to pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *vpr*, classified in class 424, subclass 199.1.

Group 4, claim(s) 1 and 14, drawn to pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *tat*, classified in class 424, subclass 199.1.

Group 5, claim(s) 1 and 14, drawn to pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *rev*, classified in class 424, subclass 199.1.

Group 6, claim(s) 1 and 14, drawn to pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *vpu*, classified in class 424, subclass 199.1.

Group 7, claim(s) 1 and 14, drawn to pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *nef*, classified in class 424, subclass 199.1.

Group 8, claim(s) 15, drawn to MVA/HIV-48 comprising SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4 and SEQ ID NO:5, classified in class 530, subclass 350.

Group 9, claim(s) 16, drawn to pLW-48 having the sequence of SEQ ID NO:1, classified in class 435, subclass 320.1.

Group 10, claim(s) 17, drawn to a plasmid vector having the sequence of SEQ ID NO:1 excluding the HIV *env*, *gag* and *pol* genes, classified in class 435, subclass 320.1.

Group 11, claim(s) 18, drawn to pLW-48 wherein the *env*, *gag* and *pol* genes have a sequence taken from another clade, classified in class 435, subclass 320.1.

Group 12, claim(s) 19, drawn to a poxvirus comprising an m7.5 promoter having the sequence of SEQ ID NO:10, classified in class 424, subclass 199.1.

Group 13, claim(s) 19, drawn to a poxvirus comprising a Psyn II promoter having the sequence of SEQ ID NO:2, classified in class 424, subclass 199.1.

Group 14, claim(s) 19, drawn to a poxvirus comprising a Psyn III promoter having the sequence of SEQ ID NO:11, classified in class 424, subclass 199.1.

Group 15, claim(s) 19, drawn to a poxvirus comprising a Psyn IV promoter having the sequence of SEQ ID NO:12, classified in class 424, subclass 199.1.

Group 16, claim(s) 19, drawn to a poxvirus comprising a Psyn V promoter having the sequence of SEQ ID NO:13, classified in class 424, subclass 199.1.

Group 17, claim(s) 20-22, drawn to a method of boosting CD8+ T cell immune response to an HIV Env, Gag or pol antigen in a primate, said method comprising administering to a primed primate a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41, classified in class 424, subclass 208.1.

Group 18, claim(s) 20-22, drawn to a method of boosting CD8+ T cell immune response to an HIV Env, Gag or pol antigen in a primate, said method comprising administering to a primed primate a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *vif*, classified in class 424, subclass 208.1.

Group 19, claim(s) 20-22, drawn to a method of boosting CD8+ T cell immune response to an HIV Env, Gag or pol antigen in a primate, said method comprising administering to a primed primate a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *vpr*, classified in class 424, subclass 208.1.

Group 20, claim(s) 20-22, drawn to a method of boosting CD8+ T cell immune response to an HIV Env, Gag or pol antigen in a primate, said method comprising administering to a primed primate a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *tat*, classified in class 424, subclass 208.1.

Group 21, claim(s) 20-22, drawn to a method of boosting CD8+ T cell immune response to an HIV Env, Gag or pol antigen in a primate, said method comprising administering to a primed primate a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *rev*, classified in class 424, subclass 208.1.

Group 22, claim(s) 20-22, drawn to a method of boosting CD8+ T cell immune response to an HIV Env, Gag or pol antigen in a primate, said method comprising administering to a primed primate a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *vpu*, classified in class 424, subclass 208.1.

Group 23, claim(s) 20-22, drawn to a method of boosting CD8+ T cell immune response to an HIV Env, Gag or pol antigen in a primate, said method comprising administering to a primed primate a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *nef*, classified in class 424, subclass 208.1.

Group 24, claim(s) 23-25, drawn to a method of inducing a CD8+ T cell immune response to an HIV Env, Gag or pol antigen in a primate, said method comprising administering to a primed primate a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41, classified in class 424, subclass 208.1.

Group 25, claim(s) 23-25, drawn to a method inducing a CD8+ T cell immune response to an HIV Env, Gag or pol antigen in a primate, said method comprising administering to a primate a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *vif*, classified in class 424, subclass 208.1.

Group 26, claim(s) 23-25, drawn to a method of inducing a CD8+ T cell immune response to an HIV Env, Gag or pol antigen in a primate, said method comprising administering to a primate a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *vpr*, classified in class 424, subclass 208.1.

Group 27, claim(s) 23-25, drawn to a method of inducing a CD8+ T cell immune response to an HIV Env, Gag or pol antigen in a primate, said method comprising administering to a primate a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *tat*, classified in class 424, subclass 208.1.

Group 28, claim(s) 23-25, drawn to a method of inducing a CD8+ T cell immune response to an HIV Env, Gag or pol antigen in a primate, said method comprising administering to a primate a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *rev*, classified in class 424, subclass 208.1.

Group 29, claim(s) 23-25, drawn to a method of inducing a CD8+ T cell immune response to an HIV Env, Gag or pol antigen in a primate, said method comprising administering to a primate a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *vpu*, classified in class 424, subclass 208.1.

Group 30, claim(s) 23-25, drawn to a method of inducing a boosting CD8+ T cell immune response to an HIV Env, Gag or pol antigen in a primate, said method comprising administering to a primate a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *nef*, classified in class 424, subclass 208.1.

Group 31, claim(s) 26-29, drawn to a method inducing a CD8+ T cell immune response to an HIV Env, Gag or pol antigen in a primate, said method comprising administering to a primate a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said primate being previously primed with a nucleic acid encoding said antigen, classified in class 424, subclass 208.1.

Group 32, claim(s) 26-29, drawn to a method inducing a CD8+ T cell immune response to an HIV Env, Gag or pol antigen in a primate, said method comprising administering to a primate a

pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol in addition to the HIV gene *vif* and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said primate being previously primed with a nucleic acid encoding said antigen, classified in class 424, subclass 208.1.

Group 33, claim(s) 26-29, drawn to a method inducing a CD8+ T cell immune response to an HIV Env, Gag or pol antigen in a primate, said method comprising administering to a primate a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol in addition to the HIV gene *vpr* and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said primate being previously primed with a nucleic acid encoding said antigen, classified in class 424, subclass 208.1.

Group 34, claim(s) 26-29, drawn to a method inducing a CD8+ T cell immune response to an HIV Env, Gag or pol antigen in a primate, said method comprising administering to a primate a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol in addition to the HIV gene *tat* and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said primate being previously primed with a nucleic acid encoding said antigen, classified in class 424, subclass 208.1.

Group 35, claim(s) 26-29, drawn to a method inducing a CD8+ T cell immune response to an HIV Env, Gag or pol antigen in a primate, said method comprising administering to a primate a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol in addition to the HIV gene *vpu* and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said primate being previously primed with a nucleic acid encoding said antigen, classified in class 424, subclass 208.1.

Group 36, claim(s) 26-29, drawn to a method inducing a CD8+ T cell immune response to an HIV Env, Gag or pol antigen in a primate, said method comprising administering to a primate a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol in addition to the HIV gene *rev* and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said primate being previously primed with a nucleic acid encoding said antigen, classified in class 424, subclass 208.1.

Group 37, claim(s) 26-29, drawn to a method inducing a CD8+ T cell immune response to an HIV Env, Gag or pol antigen in a primate, said method comprising administering to a primate a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol in addition to the HIV gene *nef* and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said

primate being previously primed with a nucleic acid encoding said antigen, classified in class 424, subclass 208.1.

Group 38, claim(s) 30, drawn to a method of making a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41, classified in class 435, subclass 69.3.

Group 39, claim(s) 30, drawn to a method of making a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *vif*, classified in class 424, subclass 69.3.

Group 40, claim(s) 30, drawn to a method of making a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *vpr*, classified in class 424, subclass 69.3.

Group 41, claim(s) 30, drawn to a method of making a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *tat*, classified in class 424, subclass 69.3.

Group 42 claim(s) 30, drawn to a method of making a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *rev*, classified in class 424, subclass 69.3.

Group 43, claim(s) 30, drawn to a method of making a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *vpu*, classified in class 424, subclass 69.3.

Group 44, claim(s) 30, drawn to a method of making a pharmaceutical composition comprising a recombinant MVA virus expressing an HIV Env, Gag and Pol and wherein the *env* gene is modified to encode for an HIV Env protein comprised of gp120 and the membrane-spanning ectodomain of gp41. Said virus additionally expresses the HIV gene *nef*, classified in class 424, subclass 69.3

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-16 are separate and distinct from each other, as they comprise differing biochemical and immunological entities having differing properties and uses. Each invention constitutes a patentably distinct antigenic composition.

Inventions 17-44 are each separate and distinct from each other as they are drawn to differing methods having different steps, different goals and leading to differing results.

Invention 1 is separate and distinct from Inventions 18-23, 25-30, 32-37 and 39-44, as the compositions of Invention 1 cannot be used in the methods of Inventions 18-23, 25-30, 32-37, and 39-44.

Invention 2 is separate and distinct from Inventions 17, 19-24, 26-31, 33-38 and 40-44, as the compositions of Invention 2 cannot be used in the methods of Inventions 17, 19-24, 26-31, 33-38 and 40-44.

Invention 3 is separate and distinct from Inventions 17-18, 20-25, 27-32, 34-39 and 41-44, as the compositions of Invention 3 cannot be used in the methods of Inventions 17-18, 20-25, 27-32, 34-39 and 41-44.

Invention 4 is separate and distinct from Inventions 17-19, 21-26, 28-33, 35-40 and 42-44, as the compositions of Invention 4 cannot be used in the methods of Inventions 17-19, 21-26, 28-33, 35-40 and 42-44.

Invention 5 is separate and distinct from Inventions 17-20, 22-27, 29-34, 36-41 and 43-44, as the compositions of Invention 5 cannot be used in the methods of Inventions 17-20, 22-27, 29-34, 36-41 and 43-44.

Invention 6 is separate and distinct from Inventions 17-21, 23-28, 30-35, 37-42 and 44, as the compositions of Invention 6 cannot be used in the methods of Inventions 17-21, 23-28, 30-35, 37-42 and 44.

Invention 7 is separate and distinct from Inventions 17-22, 24-29, 31-36 and 38-43, as the compositions of Invention 7 cannot be used in the methods of Inventions 17-22, 24-29, 31-36 and 38-43.

Inventions 8-16 are separate and distinct from Invention 17-44, as the compositions of Invention 8-16 cannot be used in the methods of Invention 17-44.

Inventions 1 and 17, 24 and 31 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the recombinant MVA virus of Invention 1 can be used to produce antibodies *in vitro*.

Inventions 2 and 18, 25 and 32 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the recombinant MVA virus of Invention can be used to produce antibodies *in vitro*.

Inventions 3 and 19, 26 and 33 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for

using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the recombinant MVA virus of Invention 3 can be used to produce antibodies *in vitro*.

Inventions 4 and 20, 27 and 34 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the recombinant MVA virus of Invention 4 can be used to produce antibodies *in vitro*.

Inventions 5 and 21, 28 and 35 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the recombinant MVA virus of Invention 5 can be used to produce antibodies *in vitro*.

Inventions 6 and 22, 29 and 36 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the recombinant MVA virus of Invention 1 can be used to produce antibodies *in vitro*.

Inventions 7 and 23, 30 and 37 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the recombinant MVA virus of Invention 7 can be used to produce antibodies *in vitro*.

Inventions 38 and 1 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the recombinant MVA viruses of Invention 1 can chemically synthesized.

Inventions 39 and 2 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the recombinant MVA viruses of Invention 2 can chemically synthesized.

Inventions 40 and 3 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the recombinant MVA viruses of Invention 3 can chemically synthesized.

Inventions 41 and 4 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the recombinant MVA viruses of Invention 4 can chemically synthesized.

Inventions 42 and 5 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the recombinant MVA viruses of Invention 5 can chemically synthesized.

Inventions 43 and 6 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the recombinant MVA viruses of Invention 6 can chemically synthesized.

Inventions 44 and 7 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the recombinant MVA viruses of Invention I can chemically synthesized.

Because these inventions are distinct for the reasons given above and the search required for the various Inventions would not be coextensive in scope, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection

are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert A. Zeman
December 15, 2004